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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,730	09/16/2005	Evert Johannes Bunschoten	0470-050738	1144

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EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,730	BUNSCHOTEN ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,20,21,23 and 25-30* is/are pending in the application.

4a) Of the above claim(s) *1-16,18,19,22,24 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,20,21,23 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 12/17/2007. Claim(s) 17, 20, 21, 23, and 25-30 are pending. Claim(s) 1-16, 18, 19, 22, 24, and 31 have been cancelled. Claim(s) 17, 20, 21, 23, and 25-30 are examined herein.

Response to Arguments

In reference to claims 28-31, Applicant's amendments have rendered the 112 first paragraph rejection with regard to disease moot and hereby withdrawn.

In reference to claims 28-31, Applicant's arguments with respect to the 112 first paragraph rejection to “prophylaxis” is not persuasive. The Examiner has interpreted “prophylaxis” to mean “prevention”. Applicant admits that prophylaxis can be divided between primary and secondary wherein primary prophylaxis refers to prevention of a disease whereas secondary prophylaxis refers to a disease that has already developed (see definition of "prophylaxis" in Applicant’s remarks). Applicant is not claiming primary or secondary prophylaxis, therefore the 112 first paragraph rejection with regard to prophylaxis is being maintained and restated in the Office Action below for Applicant’s convenience.

In reference to claims 28-30, Applicant's amendments have rendered the 112 second paragraph rejection with regard to disease moot and hereby withdrawn.

With respect to claims 17, 23, 26, 28, 30 and 31, Applicant's amendments have rendered the 102(b) rejections moot and hereby withdrawn.

In view of Applicant's amendments, the 103(a) obviousness rejection with respect to claims 18, 19, 22, 24 and 31 are moot and hereby withdrawn.

Applicant's arguments with respect to the 103(a) obviousness rejection, with respect to claims 17 and 25-30, have been fully considered but found not persuasive as Applicant is now arguing based on amended claims. Since Applicant has amended the claims, said rejection is hereby withdrawn.

Applicant's arguments with respect to the 103(a) obviousness rejection of Upohn, with respect to claims 20 and 21, has been fully considered but found not persuasive. Applicant's arguments are directed to oral dosage which is an intended use and is not given patentable weight. The following modified 103(a) rejection is shown below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-31 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the treatment of androgen deficiency, does not reasonably provide enablement for curatively,

prophylactically, or preventatively treating androgen deficiency as recited in these claims.

The instant claims are drawn to a method of curatively, prophylactically, or preventatively treating androgen deficiency. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant invention pertains to a method of curatively, prophylactically, or preventatively treating androgen deficiency.

The state of the prior art:

The skilled artisan would view that the prevention of one or more symptoms of androgen deficiency totally, absolutely, or permanently, is highly unlikely, since one cannot guarantee that these diseases will always be prevented.

The relative skill of those in the art:

The relative skill of those in the art is very high.

The predictability or lack thereof in the art:

The skilled artisan would view that the treatment to curatively, prophylactically, or preventatively treating androgen deficiency, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples:

In the instant case, no working examples are presented in the specification as filed showing how to curatively, prophylactically, or preventatively treating androgen deficiency totally, absolutely, or permanently. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Genentech, Inc. v. Novo Nordisk, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed

above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the combination in the instant claims whether curatively, prophylactically, or preventatively treating androgen deficiency totally, absolutely, or permanently.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place (US Patent 6,117,446) in view of Yamazaki (*Archive of Biochemistry and Biophysics*, 1997).

Place teaches a buccal drug delivery system that may be used in female hormone replacement therapy, in female contraception and to treat female sexual dysfunction (abstract). Place teaches that the pharmaceutical compositions comprise a therapeutic amount of an androgenic agent, a progestin, an estrogen, and a bioerodible polymeric carrier (column 4, lines 4-11).

Place further teaches that the buccal dosage units are in the form of tablets in amounts of 0.1 to about 2.5 mg of the selected androgenic agent, preferably testosterone or a testosterone ester, about 300 to 5000 μg progestin and about 50 to 500 μg estrogen. Furthermore, Place teaches that among a number of androgenic agents that may be employed, naturally occurring androgens and derivatives thereof may also be used in the formulations (column 7, lines 11-15).

Place does not specifically teach the androgen as being 15-hydroxytestosterone.

Yamazaki teaches 15-hydroxytestosterones are naturally occurring androgens in the body (page 167, Table III).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the composition comprising androgenic steroid as taught Place and used 15-hydroxytestosterone. Place teaches androgens that are naturally occurring in the body and Yamazaki teaches that 15-hydroxytesterones are found to

occur naturally in the body. Thus, one would be motivated to employ a naturally occurring androgen in the composition. The fact that 15-hydroxytestosterone is a mixture of its two isomers: 15α-hydroxytestosterone and 15β-hydroxytestosterone. Isolation and separation of isomers of a known racemate is prima facie unless there are "unexpected results," See *In re May,* 197 USPQ 601; *In re Adamson,* 125 USPQ 233; *Brenner v. Ladd,* 147 USPQ 87.

Conclusion

Claims 17, 20, 21, 23, and 25-30 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617